DENKA SEIKEN CO.,LTD.

3-4-2, Nihonbashi kayabacho, Chuo-ku, Tokyo, Japan 103-0025

DEC 0 4 2001

I. 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is: K011958

(A)(1) Submitter's name: Denka Seiken Co., Ltd.

Submitter's address: 3-4-2, Nihonbashi kayabacho,
Chuo-ku
Tokyo, Japan 103-0025

Submitter's telephone number: (03) 3669-9421

Contact Person: Mr. Yousuke Meguro
Assistant Manager
International Sales and Business Development Dept.

Date Summary Prepared: June 20, 2001

(2) Trade or proprietary device name: CRP-Latex (II) SEIKEN High Sensitivity Assay
Common or usual name: C-reactive protein (II) Assay
Classification Name: C-reactive protein immunological test system
Panel: Immunology
Class: II

(3) Legally marketed predicate device: N High Sensitivity CRP Assay
[Dade Behring Inc,](K991385).

(4) Subject device description:

The CRP-Latex (II) SEIKEN High Sensitivity Assay Kit is a latex *in vitro* diagnostic immunoassay for the quantitative determination of C-reactive protein in human serum. Antigen in the sample bonds to the specific anti-CRP antibody, which has been adsorbed to latex particles, and agglutinates. The agglutination is detected as an absorbance change when read on an automated analyzer (the Hitachi 717 was used for these studies), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

(5) Subject device intended use:

DENKA SEIKEN CO.,LTD.
3-4-2, Nihonbashi kayabacho, Chuo-ku, Tokyo, Japan 103-0025

The CRP-Latex (II) SEIKEN High Sensitivity Assay Kit is a quantitative assay for use with an Automated Analyzer for the determination of C-reactive protein in human serum and plasma. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury, and inflammatory disorders.

(6) Performance data:

The CRP-Latex (II) Seiken High Sensitivity Assay and the predicate device, N High Sensitivity CRP Assay have only minor difference that do not affect the performance, safety or effectiveness of the measurement.

Comparative performance studies conducted on 70 donor samples yielded a high correlation coefficient upon comparison of the CRP –Latex (II) Seiken High Sensitivity and the predicate device, N High Sensitivity CRP. The correlation coefficient r = 0.999; slope = 1.034, y intercept = -0.173 (Least squares); slope = 1.014, y intercept = -0.094 (Passing/Bablock). Supportive clinical data from 388 normal adult donor samples confirm this finding, with correlation coefficient r = 0.996.

Precision studies, both within run and between day studies, were performed using three levels of control material. % CV for Level 1 did not exceed 1.81%; for Level 2, % CV did not exceed 1.65%; and for Level 3, % CV did not exceed 1.3%.

The lower level of detection (sensitivity of the assay) is at 0.05mg/L, with the assay range up to 10.0 mg/L.

These findings serve to demonstrate that the performance of the CRP-Latex (II) Seiken High Sensitivity Assay kit is substantially equivalent to the predicate device, N High Sensitivity CRP (Dade Behring).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

De.Seiya Sato, Ph.D.
Plant Director
Denka Seiken Co., Ltd.
3-4-2, Nihonbashi-Kayabacho, Chuo-Ku,
Tokyo, Japan 103-0025

DEC 0 4 2001

Re: k011958
Trade/Device Name: CRP-Latex (II) SEIKEN High Sensitivity Assay Kit
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: September 28, 2001
Received: October 1, 2001

Dear Dr. De. Seiya Sato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): K011958

Device Name: CRP-Latex (II) SEIKEN High Sensitivity Assay Kit High Sensitivity Assay Kit

Indications for Use:

The CRP-Latex (II) SEIKEN High Sensitivity Assay kit is a quantitative assay for use with an Automated Chemical Analyzer for the determination of C-reactive protein in human serum and in heparinized and EDTA-plasma. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury, and inflammatory disorders.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011958

Prescription Use X or Over-the-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)